Claims 22-34 have been added. Support for these claims is found in the specification at, for example, page 1, lines 9-11; page 3, lines 13-19; Examples 3 and 4; and original claims 1-13. *See*, *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

It is submitted that no new matter has been introduced by these claims. Approval and entry of the claims is respectfully solicited.

Obviousness Rejection

Claims 1-13 were rejected under 35 USC § 103(a) as being unpatentable over Schmidt *et al.*, U.S. Patent No. 4,605,666 ("Schmidt") in view of Newlin, U.S. Patent No. 3,615,591 ("Newlin"), Chiralt *et al.*, 1999 IFT Annual Meeting ("Chiralt") and Hussaini et al., "A Guide to Halal Food Selection" (1993) ("Hussaini"). (Paper No. 9 at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Schmidt discloses a powder containing a water-soluble vitamin prepared by spray drying an aqueous slurry of the vitamin and a binder, a lubricant, and optionally an adsorbent and an additional excipient. (Col. 1, line 52 - Col. 2, line 54).

Newlin discloses a method of making "a peanut butter-jelly product so that not only is there no whitening or dark color penetration on the peanut butter, but also there is no surface discoloration of the peanut butter at the peanut butter-jelly interface." (Abstract.)

Chiralt discloses the "combined vacuum impregnation-osmotic dehydration in cryoprotection of apple." (Title.) Chiralt discloses that "[c]hanges in

sample color ... after the freezing-thawing process were quantified to evaluate the cryopreservative effect of the VI-OD treatments." (Abstract.) "The most effective pretreatments in order to preserve sample color were those involving VI with pectin, where no significant browning was detected in apple samples after thawing." (*Id.*)

Hussaini discloses the "Islamic status for the permissibility of various food additives." (Title.) Hussaini discloses that pectin is used as a "suspending agent, [and] improves colour." (Page 3, No. 56.)

In making the rejection, the Examiner asserted that Schmidt discloses "a powder or tablet composition, comprising a water-soluble vitamin (i.e., sodium ascorbate, ascorbic acid, calcium ascorbate, etc...); a binder (i.e., microcrystalline cellulose, etc...); a lubricant (i.e., stearic acid, magnesium stearate, calcium stearate, etc...) and an excipient (i.e., pectin, starch, etc...)." (Paper No. 9 at 3.) The Examiner further asserts that Schmidt "discloses that 'the components described herein are added in amounts such that the final powder formed will contain at least 80% (preferably at least 90) percent by weight of the water soluble vitamin, less that 15 (preferably less than 9) percent by weight of binder ... 0.2 to 5 percent by weight of the lubricant and less than 3 percent of other excipients ... those skilled in the art may discover better proportions with them and for specific purposes.'" (*Id.* at 3-4.)

The Examiner acknowledged, however, that Schmidt "differs from the claimed invention in 1) the specific amounts of pectin in the composition, about 0.1 to about 10%, more specifically about 0.5 to 5%, based on the total weight of the composition; 2) 95-99% by weight of L-ascorbic acid and or a pharmaceutically

acceptable salt; 3) the use of citrus pectin; and 4) the functional characteristic of pectin as a binder." (*Id.* at 4.)

To fill the acknowledged gap, the Examiner relied upon either Newlin or Chiralt as disclosing "the use of pectin as an effective anti-browning agent," and Hussaini as disclosing "the use of pectin as an effective color-improving agent." (*Id.*)

The Examiner then asserted that Schmidt "makes clear that the selection of secondary ingredients such as microcrystalline cellulose, stearic acid or magnesium stearate and pectin in a vitamin C (e.g., sodium ascorbate and ascorbic acid) powder or tablet is old and well know in the art," and that "optimization of amounts of known active and secondary ingredient(s) in a composition is well considered within the skill of the artisan." (*Id.*)

The Examiner also asserted that "[o]ne having ordinary skill in the art would have been ***motivated to employ*** pectin in vitamin C composition such that ***the stability of color of the claimed composition would be significantly improved***," and that one would have been "***motivated to select*** well known anti-browning agent or color improving agent such as ***pectin to prevent browning or improve coloring of claimed composition*** containing L-ascorbic acid and/or its salts." (*Id.*)

The Examiner then concluded "the references make obvious the claimed invention" and that "the selection of citrus pectin among pectins is well considered within the skill of the artisan, absent evidence to the contrary." (*Id.* at 4-5.)

Initially, we note that the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ

785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

As is well settled, a rejection under § 103 must demonstrate ***where*** in the cited documents there was a suggestion which would have "strongly motivated" one to carry out the invention as claimed. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1986). The type of motivation which would have "***impelled***" one to do so (*Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes "***should***" be made. *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964). The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine "***must be based on objective evidence of record***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

The discussion of the secondary documents, however, takes up only two lines in the rejection and reads in its entirety: "Either Newlin or Chiralt teaches the use of pectin as an effective anti-browning agent. Hussaini teaches the use of pectin as an effective color-improving agent." (Paper No. 9 at 4.) These assertions identify nothing in Schmidt or the secondary documents that discloses or suggests their combination to arrive at the claimed invention. Thus, the rejection fails to provide any reason why one would be motivated, let alone impelled, to combine the references in the manner suggested by the Examiner. Thus, the rejection fails to set forth the required facts and reasoning required to support a *prima facie* case of obviousness. For this reason alone, the rejection should be withdrawn.

We also note that the rejection uses the wrong standard for determining obviousness. The rejection relies upon "***motivated to employ***" and "***motivated to select***" standards that are not found in the statute or precedential authority. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would ***impel*** one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). Accordingly, the rejection is insufficient as a matter of law, and should be withdrawn for this reason also.

We further note that all of the secondary documents disclose the use of pectin in food products: Newlin discloses a peanut butter-jelly composition; Chiralt discloses a vacuum impregnated-osmotically dehydrated apple; and Hussaini discloses the use of various food additives in Islamic foods. Schmidt, on the other hand, discloses a powder containing a water-soluble vitamin, for use in making vitamin tablets. The rejection, however, identifies no disclosure or suggestion in any of the cited documents that food additives of the secondary documents would be useful in making the tableting compositions of Schmidt. And, the rejection does not identify where in the secondary documents there is a disclosure or suggestion to use water-soluble vitamins. Thus, the rejection is left with a factual gap – it does not identify why one would look to food additive disclosures to solve a binding problem for tableting water-soluble vitamin compositions. There is simply no motivation or suggestion to make the proposed combination. And, even if the proposed combination is made, the rejection provides no evidence from any of the cited documents as to how one would

modify the pectin levels to achieve the presently claimed binding properties. At best, the documents might suggest optimizing color stabilization. But, the rejection provides no evidence that optimizing color stability would lead to the presently claimed binder. Accordingly, the rejection is factually insufficient to support a rejection under § 103 and should be withdrawn for this additional reason.

Further, the rejection admits that Schmidt fails to disclose the use of citrus pectin. The rejection fails to identify ***why*** one skilled in this art would modify the disclosure of Schmidt to employ citrus pectin to arrive at the claimed invention. The rejection merely asserts that "the selection of citrus pectin among pectins is ***well considered*** within the skill of the artisan." (Paper 9 at 5.) Again, "well considered" is not the proper standard under § 103, and even if it were, the rejection fails to identify where, in any of the cited documents, there is a disclosure or suggestion as to use of citrus pectin in the manner claimed. Accordingly, there is no evidence of record to support the proposed combination in the rejection. Thus, the Office Action is insufficient to support a rejection under § 103, and the rejection should be withdrawn for this reason too.

With a view toward furthering prosecution, claims 1 and 8 have been amended to recite that the binder consists of about 0.1 to about 10% of pectin. The rejection identifies no disclosure or suggestion in any of the cited documents where pectin is the exclusive binder in a powder or a compressed tablet containing L-ascorbic acid as recited in amended claims 1 and 8. For this reason, as well, the rejection should be withdrawn.

Claims 22-34 have been added as noted above. Independent claims 22 and 29 recite that the composition has a compressibility that is superior to the compressibility of the same composition having a standard binder. (*e.g.*, starch or hydroxypropylmethylcellulose (HPMC)) in place of the pectin binder. The rejection fails to identify any disclosure or suggestion in any of the cited documents that pectin in the amount recited in claims 22-34 would produce, inherently or otherwise, the superior compressibility obtained with the claimed invention. (*See e.g.*, Examples 1-4 comparing the compressibility of a composition having solely a pectin binder to a conventional composition having a HPMC binder). Accordingly, it is submitted that claims 22-34 are allowable over the documents of record.

For the reasons set forth above, entry of the amendments and added claims, withdrawal of the rejections, and allowance of the claims is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Non-Fee Amendment, Commissioner for Patents, Washington, D.C. 20231, on September 27, 2002.

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Respectfully submitted,

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In re Application of: Chyi-Chen[redacted]HEN *et al.*
Parent Serial No.: 09/738,61[redacted]
For: **L-ASCORBIC ACID AND PECTIN COMPOSITION**

MARKED-UP VERSION OF AMENDED CLAIMS

1. (Twice amended) A powder or granule composition comprising:

(a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof, and

(b) a binder consisting of about 0.1 to about 10% by weight of pectin [binder], calculated based on the total weight of the composition thereof.

8. (Twice amended) A compressed tablet formed from a powder or granule composition comprising:

(a) L-ascorbic acid and/or a pharmaceutically acceptable salt thereof, and

(b) a binder consisting of about 0.1 to about 10% by weight of pectin [binder], based on the total weight of the composition.